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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PATTEN, PATRICIA A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02 11 2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,588

Applicant(s)

Su et al.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 23, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) 13-23, 27, and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 13-17 added in Paper No. 8 have been renumbered 24-28.

Claims 1-28 are pending in the application.

Claims 13-23 were elected without traverse by Applicants in Paper No. 3 and consequently withdrawn from further consideration on the merits as being drawn to a non-elected invention in Paper No. 4.

Newly submitted claims 27 and 28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 27 and 28 are respectively drawn to a method for inhibiting, preventing and reversing cell membrane disruption and inhibiting, preventing and reversing protein oxidation. These methods were not originally examined on the merits. Claims 27 and

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28 are properly restrictable because these methods could be performed without performing the methods of claims 1-9 and 24-26. Further, the search for these methods would not be co-extensive, posing a burden of searching on the Examiner.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-28 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-12 and 24-26 have been presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24 states '...consuming an additional supplement together with said processed *Morinda citrifolia*', and claim 25 states '...wherein said processed *Morinda citrifolia* further comprises an additional supplement...' It does not appear that there was any disclosure as originally filed which was directed toward the addition of a supplement with *Morinda citrifolia*. Thus, this is considered New Matter.

It is suggested that the New Matter be deleted from the claims in order to overcome this rejection.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 states 'wherein said processed *Morinda citrifolia* further comprises an additional supplement...'. It is not understood how the *Morinda citrifolia* could contain an additional supplement *per se* because the claim does not state 'composition comprising'. Thus, the recitation of 'further comprises' is awkward in that *Morinda*

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citrifolia juice is juice and cannot be anything else. It is thought that applicants mean that the composition comprises *Morinda citrifolia*, and that the composition further comprises an additional supplement. Alternatively, Applicants may wish for the method to include an additional step; i.e., 'wherein the method further comprises the step of administering a supplement', but the Examiner is not sure. The claim has been examined as if claim 1 was drawn to '....consuming on an empty stomach a composition comprising more than one fluid ounce...', and if claim 25 recited 'wherein the composition further comprises an additional supplement which works in conjunction....' for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 9 and 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Mueller et al. (2000).

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Mueller et al reported that noni juice (*Morinda citrifolia*) was known and used in the art at the time the invention was made. Mueller et al. studied the potassium content of noni juice sold by Body Systems Technology (p.310). The product contained noni fruit juice, white grape juice, flavors and Flower of Benjamin. Although the recommended dosage of noni juice was typically suggested at one ounce per day, Mueller et al. disclosed that people had reportedly drank noni juice at a concentration of one ounce per day or greater (p.311). Because the reference states 'juice' with regard to the patients which were ingesting the noni juice at more than one ounce per day, it is deemed that the reference means pure juice, which would equal 100%, thereby anticipating the claims.

The language 'inhibiting, preventing and reversing cell membrane disruption' is merely an inherent property of the method which would have naturally manifested as a result of drinking the juice.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-12 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al. (2000) in view of Gagnon (1997).

The teachings of Mueller et al. were discussed *supra*. Mueller et al. further reported that a patient with chronic renal insufficiency began drinking a shot glass of noni-juice before each meal (daily) (p.310). Again, they reported that although the recommended dose of noni juice was primarily found to be one ounce per day, Mueller et al. discovered that many people were drinking the juice at a higher concentration, which would constitute more than one ounce per day (p.311).

The reference did not specifically state wherein the patients consumed the noni juice on an empty stomach, nor did the reference specifically teach manufacturing methods for the fruit.

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Gagnon (1997) suggested '...taking extracts between meals, apart from food, because that is when they are more easily absorbed by the body. This way ,extracts enter the bloodstream readily and immediately start the healing process' (p.27).

The ordinary artisan would have been motivated to have ingested the noni juice on an empty stomach in order to have allowed the juice to be absorbed by the body more readily, thereby obtaining the maximum medicinal benefit of the juice.

The language 'for inhibiting, preventing, and reversing lipid peroxidation' or 'scavenging lipid hydroperoxides and superoxide anion free radicals' *would have merely been an intrinsic consequence of drinking the noni juice in the claimed amounts.* The claimed method comprises drinking the juice of *Morinda Citrifolia*. Thus, because drinking *Morinda Citrifolia* was being practiced in the art, it must have intrinsically manifested these claimed results.

Further, the term 'processed' is not clearly defined within the specification. It is clear that in order to obtain 'juice' the fruit must be squeezed to obtain the juice or the juice may be obtained via allowing the fruit to ripen to collect the juice. Although the references did not specifically recite the term 'processed' it is deemed that the method

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for obtaining the juice is inconsequential. Allowing the fruit to ripen to collect the juice, or mixing the fruit and filtering to obtain juice or squeezing the fruit to obtain the juice would have all been methods well known to one of ordinary skill in the art. *Absent clear, convincing evidence to the contrary which would indicate that the method of 'processing' the noni juice actually materially changed the composition of the invention, it is deemed that the method for obtaining the Morinda Citrifolia juice was a matter of judicious selection, and would not impart any difference in the juice.*

Although the references did not specifically teach wherein the fruit is harvested when it is at least one inch long and up to twelve inches in diameter, wherein the fruit is cleaned, harvested, separated from spoiled fruit and placed in plastic lined containers, wherein the juice is separated from the solids of the fruit such as seeds, peel or pulp, mixing the juice with a flavor or sweetener for example and heating the dietary supplement to a temperature of at least 181°F, wherein the supplement is packaged in a glass or plastic container, and wherein the supplement includes reconstituted *Morinda citrifolia* fruit juice from pure juice puree of French Polynesia.

Specific limitations regarding harvesting, cleaning, or wherein the juice was separated from the solids of the fruit or wherein the fruit is mixed with a sweetener does not materially change the method. The term 'juice,' as defined by Webster's Dictionary, means 'the liquid part of a plant, fruit, or vegetable.' Further, Hirazumi et al. explained

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that they allowed the juice to seep out of the fruit. Thus, it is deemed that the liquid of the fruit was separated from solids such as the seeds and the peel.

It was routine in the art of pharmacology to admix active ingredients with carriers, colorings and sweeteners for example. Carriers were an advantageous means of diluting active ingredients to necessary dosage ranges. Further, sweeteners and colorings would not have changed the medicinal qualities of the noni. One of ordinary skill in the art would have been motivated to have added carriers and sweeteners to noni juice in order to have formulated noni juice compositions containing varying percentages of active ingredients (i.e., 'regular' -vs- 'extra strength') as well as for mere ease of delivery.

It was also routine in the art to heat pharmaceutically active ingredients obtained from natural sources to temperatures to about 181° F in order to kill any potential bacteria/fungus which may have been present. One of ordinary skill in the art would have been motivated to have heat-killed the juice in order to eliminate any bacteria or fungus which may have had the potential to make a patient ill.

Although the reference does not teach wherein the noni fruit is harvested when it is at least one inch long and twelve inches in diameter, the Examiner deems that the fruit, containing intrinsic phytochemicals, would have contained these phytochemicals (active ingredients) at most of the growing stages of the fruit. The Examiner cannot find any evidence within the Instant specification which clearly indicates that the harvesting

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limitations found in the claims materially changes the characteristics of noni. Thus, it is deemed that the method for harvesting does not clearly change the method for , since the juice, is substantially the same juice as described by Mueller et al. especially lacking clear, credible evidence to the contrary.

Further harvesting limitations such as separating spoiled fruit, and placing the harvested fruit in a plastic container does not materially change the method. Applicants are merely reciting pre-operative steps which do not limit the method for reducing cellular damage.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The majority of Applicants' arguments pertain to prior rejections and are thus moot in light of the new rejections. However, arguments focusing on the 'processed' *Morinda citrifolia* will be answered.

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Applicants argue that '...the present invention relies on the specific processing procedures used to create a unique finished *Morinda citrifolia* product' (p. 2-Arguments). As stated supra, Applicants have not provided information that would clearly demonstrate that the method for processing the *Morinda citrifolia* would actually yield a juice which is novel from the noni juice known in the art.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER R. TATE
PRIMARY EXAMINER